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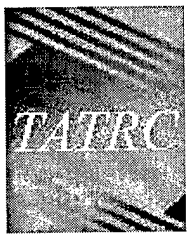


Effect of Computer Systems and Electronic Communication on Asthma Outcomes
Proposal Number: 1999000148

Stephen Lewis Schmidt M.D.

Abstract

Problems

•Medical Research and Material Command, Office of Regulatory Compliance and Quality (MRMC RCQ) Review The primary problem encountered was obtaining the RCQ review. The need for this step in the research process was part of the initial grant process. Additionally, the local Investigation Review Board (IRB) had already approved the protocol when the need for this step was communicated several months after the grant was awarded. The development and testing of the system progressed to the point of having potential patients test the system by entering baseline data, however, this progress was immediately stopped under guidance from the RCQ reviewer. The initial information was forwarded to RCQ in November of 2000, and all requested revisions were forwarded in early January of 2001. However, review is still pending at the time of this report, and therefore, the clinical trial of the system still awaits RCQ approval. This has made completion of the project unfeasible due to funding short falls given this unexpected and prolonged administrative delay.

•Time Line The time line became a problem due to two main issues. First, as was mentioned in the midterm report, the funding disbursement and duration. Notification and disbursement were not obtained until March of the award year. This allowed little time for resource allocation prior to the end of the fiscal year. Additionally, the "front-end" funding required allocation of funds prior to the end of the fiscal year in September. This allowed only six months for research prior to having all funds contractually obligated. This reduces the investigator's ability to use resources for unanticipated costs and creates inefficiency as "best-guess" amounts are allocated. Once funding allocation is made, completion of the contracting process proved to in direct conflict with the tight time-lines required by the funding stream. Great effort was spent letting contracts only to have great delays in hardware and personnel acquisition.

•Information Management Division (IMD) Due to the high tech nature of the project,

IMD support was pivotal to any success. However, we depended on the local assets for support and these proved inadequate for two reasons. First, like so many other areas within the MTF's, their personnel feel overwhelmed with existing missions and resources. Therefore, their willingness and ability to provide support were less than optimal in spite of prior coordination. Second, when support was available, their knowledge of the state-of-the-art systems being used to develop the tool was limited, and we were unable to anticipate problems before they would occur. . This was demonstrated when Dr. Suykerbuyk informed the Microsoft software engineers of a problem and solution within their Internet Explorer 5.0. Therefore, Dr. Suykerbuyk had to perform the majority of support tasks for the server, web site, and data base management. This greatly slowed progress on the project design and testing due to our underestimation of the provider time required to address these issues. Finally, deployment of our system was required behind the MTF firewall leading to administrative delays as it was altered to meet AMEDD regulations.

•Deployments A foreseen challenge unique to research by military physicians is the primary mission of troop support. However, the magnitude of the challenge was unforeseen. During the first 12 months of research, the deployments for two weeks in support of Field Training Exercises, 3 months for Officer Basic Course, and then 6 months in support of Operation Joint Forge in Bosnia. In spite of this, progress continued on system development and testing and the clinical study was on schedule to provide data with a six-month extension were the RCQ review not still pending.

•Interface As the system was developed, several problems were identified with the desktop computer interface. First, systems were not funded as part of our original proposal to assure provider access to the Internet and web site resulting in our providers having restricted access to computers providing the interface and capable of handling the software. Additionally, an unexpected problem arose when 3 of 67 patients initially contacted were unwilling to participate in the study due to the need to support a desktop interface.

Deliverables

A comprehensive, web-enabled disease management system has been developed and tested. The system queues the patient on a daily basis to enter peak flows, symptoms, and take medications. This addresses the barrier of compliance on a daily basis. The software then analyzes the data for worsening disease state according to Peak Flow as a percentage of personal best and variance to provide improved disease assessment. (See Graph). If no worsening occurs, the patient remains in the monitoring state and data is updated to the server in real time. Additionally, during the daily interaction, educational resources from the Breath Easy CD developed by the Center for Total Access, Ft. Gordon, GA were integrated into the web-driven system. This provides education via repetitive exposure that is more effective than the common "flooding" technique used in provider offices.

If the patient's disease state worsens, the system assists the patient in disease assessment, early symptom recognition, and early intervention. In addition, recommendations are provided to the patient at that moment from the patient's individualized treatment plan from their provider (See Figure with Treatment Plan). This facilitates early intervention without access barriers and provides the potential for decreased utilization.

For the provider, an email is sent notifying of them of the worsening disease state. The provider can then log on to the web site and view the patient's recent data (See Figure with Graph). If necessary, they can also review the DoD Asthma Clinical Practice Guideline to address specific issues and provide focused provider education. Finally, providers can update the patient's treatment plan, and these changes are automatically reflected on the patients computer at home. This allows "virtual" access to the provider, which assists in placing the right patient in the right place at the right time. By triaging our asthmatic patients we assure only those needing evaluation access the system. This results in more appointments available for TRICARE Prime and TRICARE for Life patients.

The deliverable differs from the original proposal in that it has yet to be tested in a clinical setting to evaluate its effect on clinical outcomes.

Expenditures

	3Q FY 00	4Q FY 00	1Q FY 01	2Q FY 01	
Element of Resource (EOR)	Apr 1 - May 31	Jun 1 - Sep 30	Oct 1 - Dec 31	Jan 1 - Mar 31	TOTALS
Travel 2100	1,047.00	0.00	0.00	0.00	1,047.00
Shipping 2200	6.90	0.00	60.00	0.00	66.90
Rent & Communications 2200	0.00	0.00	0.00	0.00	0.00
Contract for Services 2500	285,800.00	0.00	0.00	0.00	285,800.00
Supplies 2600	3,939.91	0.00	0.00	0.00	3,939.91
Equipment 3100	225,954.33	0.00	0.00	0.00	225,954.33
GRAND TOTALS	516,748.14	0.00	60.00	0.00	516,808.14

Financials

Due to the research awaiting review by the CRQ, minimal additional costs were incurred. However, we continued to draw on our contracts for services.

Major changes from the original proposal were as follows:

Since the clinical trial was never conducted, statistics were not generated for analysis, resulting in a savings of $5,000.

A new, free Internet service provider was identified resulting in a savings of $30,000

A local router was used resulting in a savings of $19,800.

Personnel costs were higher due to extended time line and redundant work, this is reflected in the $47,900 above budget for the midlevel provider, nurse, and administrative assistant.

Final Results

As already described in the Deliverables section, a computer-based, web-enabled chronic disease management system was created as the result of the project.

The potential for AMEDD However, in order for this to occur, the system must undergo clinical testing.-wide deployment of this system is tremendous given the number of asthmatic beneficiaries. It's universally accessible engine can be used for beneficiaries regardless of location in reference to their Primary Care Manager.

Projected Costs

The projected cost of a pilot study followed by a larger, multi-center clinical trial will be: Pilot Multi Center Trial Item Cost Projection Patient Interface $50,000 $150,000 Nurse Coorinator $40,000 $100,000 Admin. Assistant x1 yrs $20,000 $50,000 IT Expert / Support $50,000 $50,000 Statistician $10,000 $30,000 Admin. Costs $10,000 $50,000 TDY $5,000 $25,000 1 FTE M.D. Investigator $160,000

TOTAL $185,000 Total $615,00

Once the studies are complete, however, further costs will be minimal compared to the potential benefits. A central server can be used for each RMC. This can then be used by all providers and asthmatic patients with Internet access. Personnel and upkeep expenses estimated will be minimal. The estimated cost per region per year is $30,000.

Comments

This program is an outstanding tool for the advancement of military medicine. However, the importance of changing the administrative structure cannot be over-emphasized. This will result in better support of investigators and increasing the yield of the DoD investment in research on cutting edge technology in medicine.

The following suggestions resulted from our project: 1. RCQ Review – While the need for this type of quality assurance is well understood, adequate resources should be dedicated to expediting this review. This would mortal delays such as occurred in this project do not occur in the future.

2. Funding – Investigators must be able to have their funds cross fiscal years without fear of resource losses.

3. Contracting – Central support from P8 to expedite contracts for capital and personnel acquisition would greatly streamline the timeline of future research projects.

4. Flexible Time Lines – Unique to active duty investigators is the spectre of deployment in support of our primary mission. The flexibility shown by P8 during this project with the 6 month extension would have allowed for completion of the study in spite of these challenges. That flexibility must be maintained and extended in support of active duty investigators.

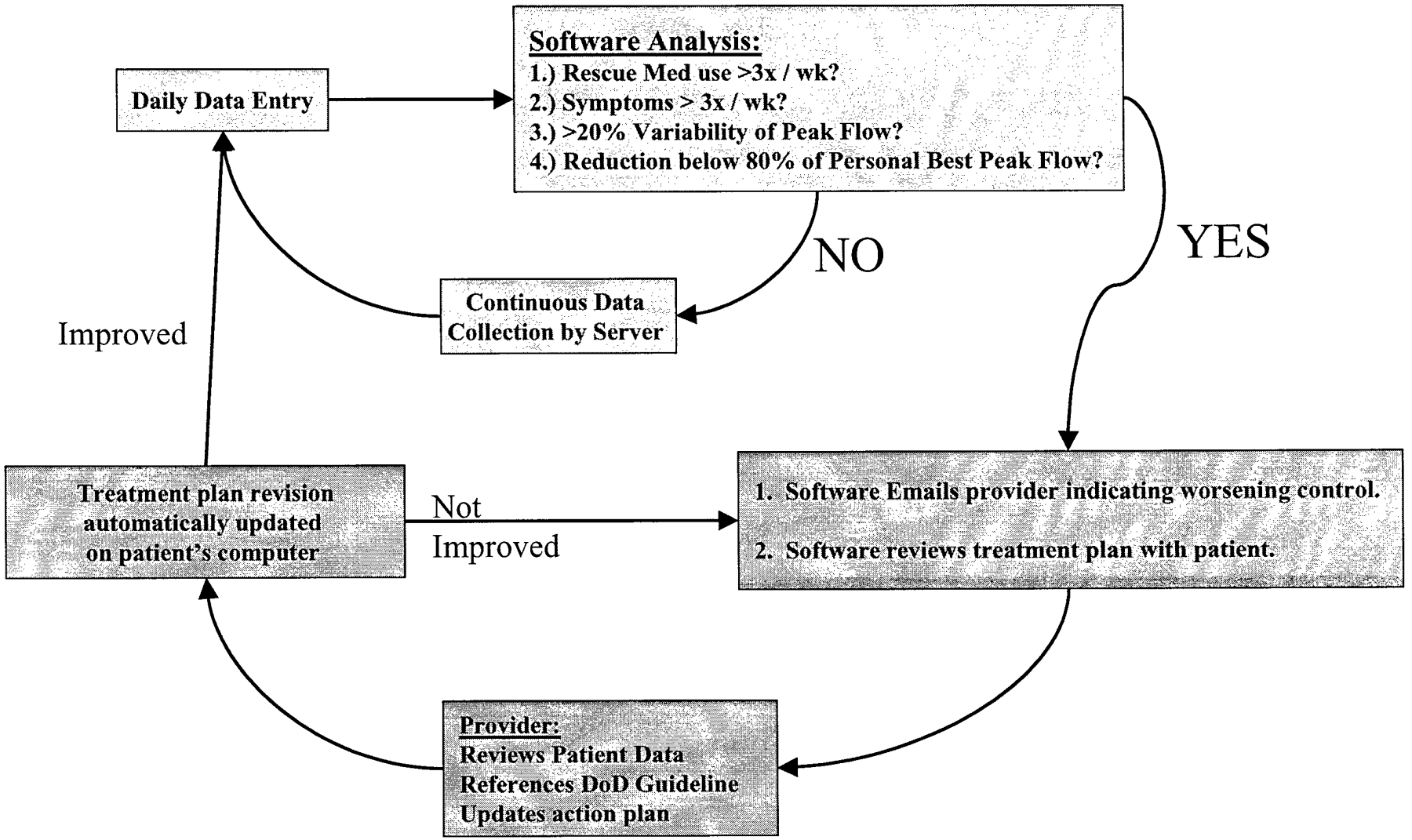
TATRC Scientific Review

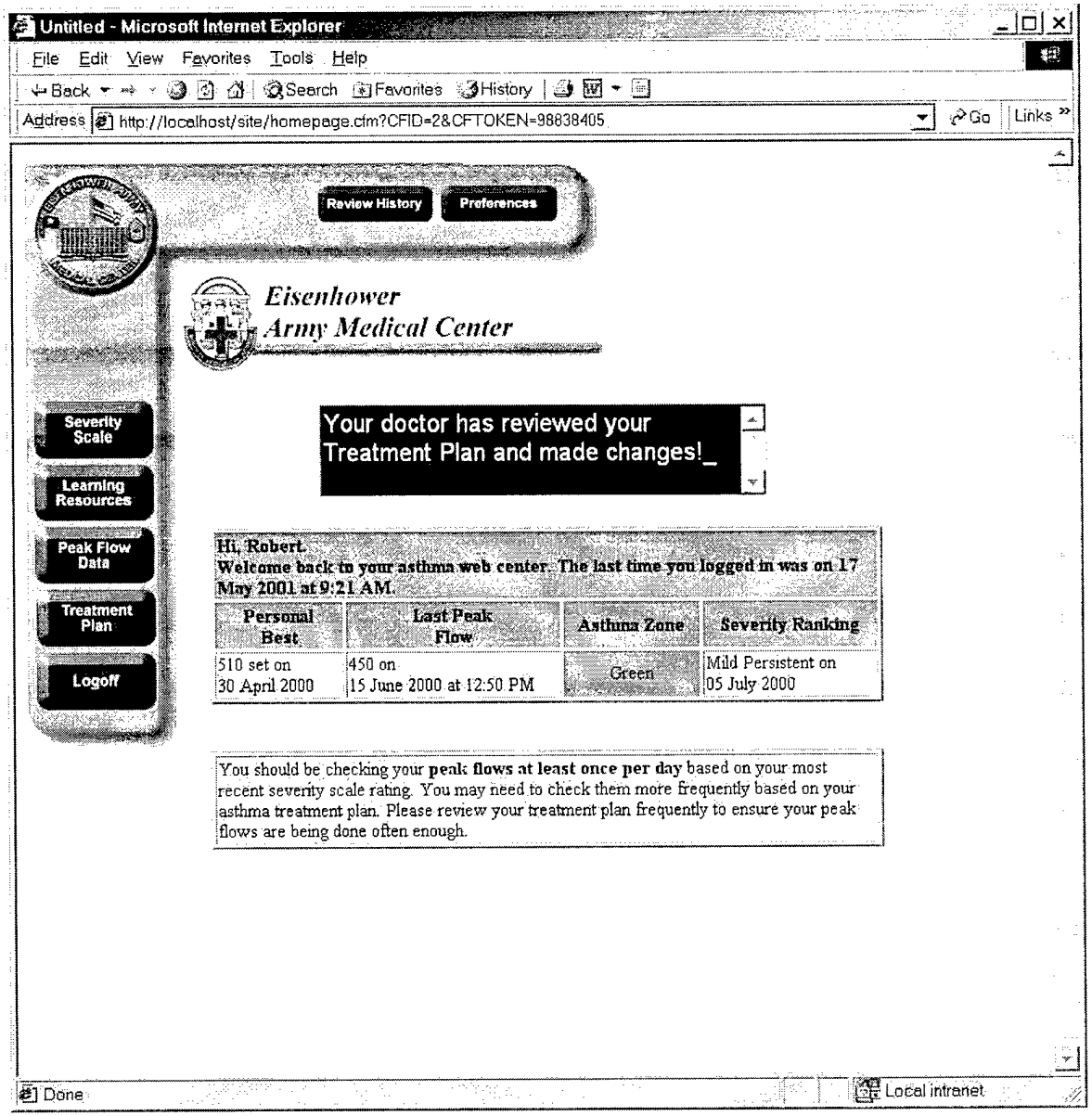
TATRC Acquisition Review

Supporting Graphs/Charts

See Attached

Disease Management Model

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Army Medical Center
Severity Scale
Learning Resources
Peak Flow Data
Treatment Plan
Logoff
Your doctor has reviewed your Treatment Plan and made changes!_
Hi, Robert.
Welcome back to your asthma web center. The last time you logged in was on 17 May 2001 at 9:21 AM.
Personal Best
Last Peak Flow
Asthma Zone
Severity Ranking
510 set on 30 April 2000
450 on 15 June 2000 at 12:50 PM
Green
Mild Persistent on 05 July 2000
You should be checking your peak flows at least once per day based on your most recent severity scale rating. You may need to check them more frequently based on your asthma treatment plan. Please review your treatment plan frequently to ensure your peak flows are being done often enough.
Done
Local intranet

Untitled - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites History

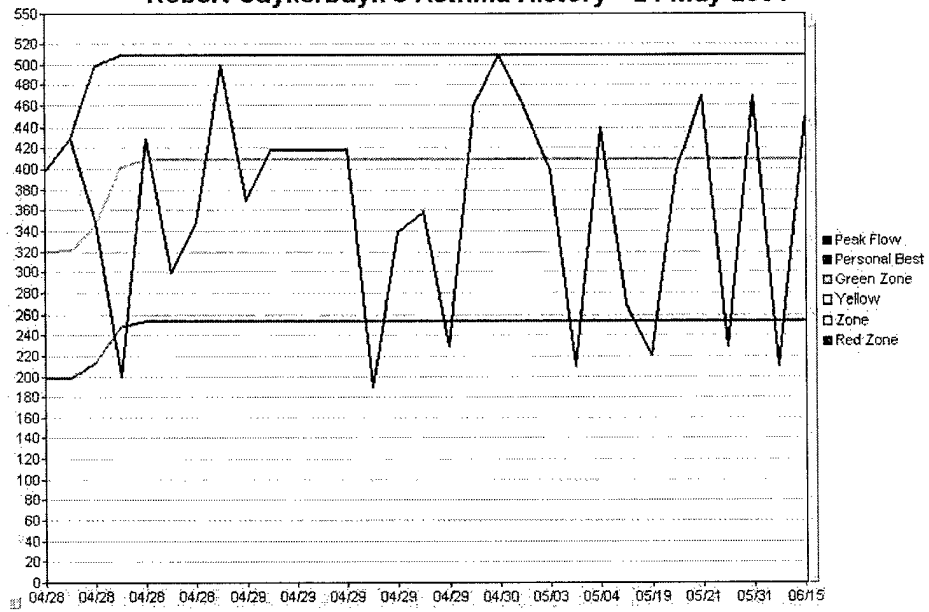
Address http://localhost/site/Graph.cfm?selectID=5&firstname=Robert&lastname=Suykerbuyk Go Links

Eisenhower Army Medical Center

Go to Patient's treatment plan

Return to Homepage

Robert Suykerbuyk's Asthma History - 24 May 2001



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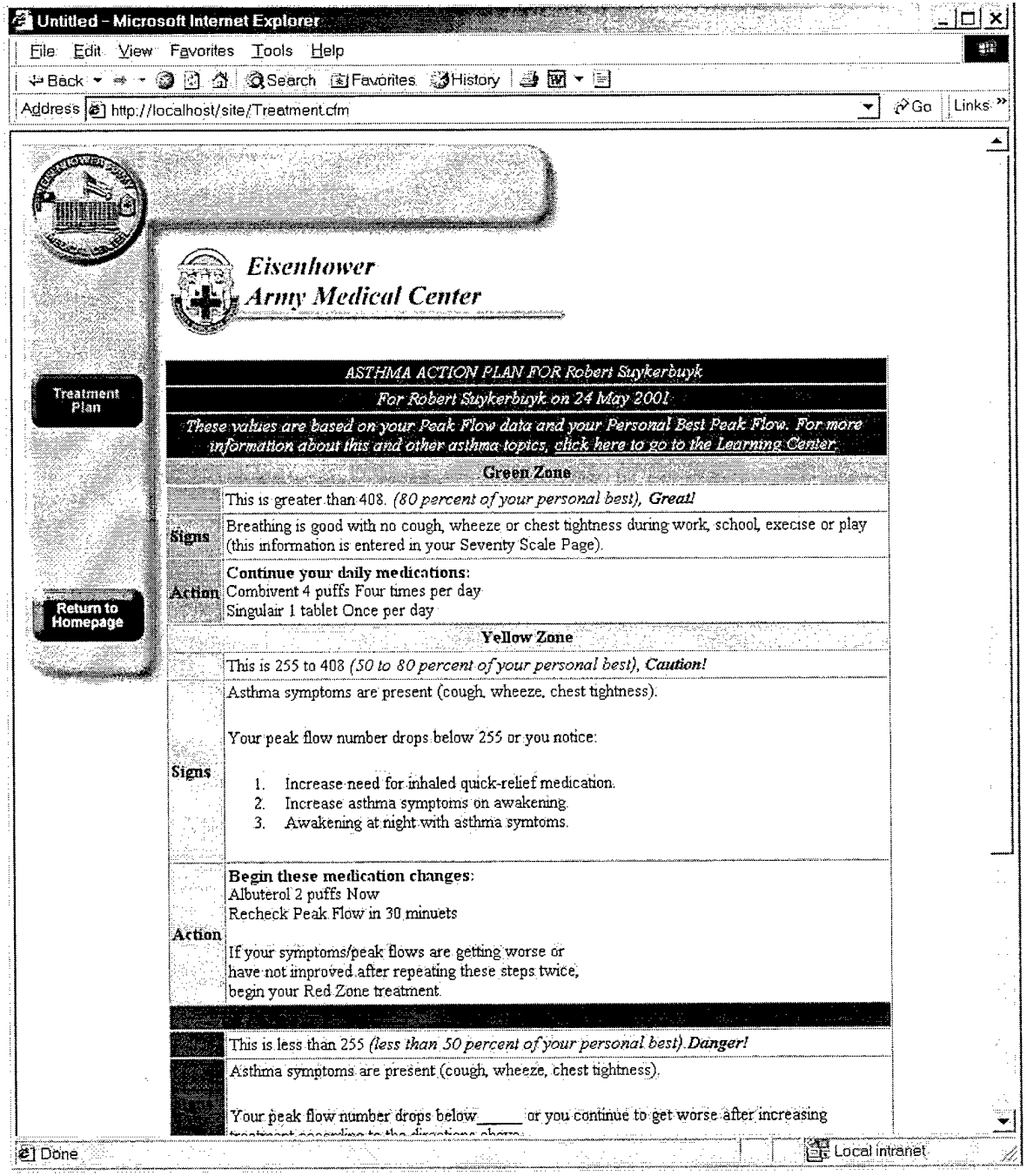
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Address http://localhost/site/Treatment.cfm
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Eisenhower
Army Medical Center
Treatment Plan
Return to Homepage
ASTHMA ACTION PLAN FOR Robert Suykerbuyk
For Robert Suykerbuyk on 24 May 2001
These values are based on your Peak Flow data and your Personal Best Peak Flow. For more information about this and other asthma topics, click here to go to the Learning Center.
Green Zone
This is greater than 408. (80 percent of your personal best), Great!
Signs
Breathing is good with no cough, wheeze or chest tightness during work, school, exercise or play (this information is entered in your Seventy Scale Page).
Action
Continue your daily medications:
Combivent 4 puffs Four times per day
Singulair 1 tablet Once per day
Yellow Zone
This is 255 to 408 (50 to 80 percent of your personal best), Caution!
Signs
Asthma symptoms are present (cough, wheeze, chest tightness).
Your peak flow number drops below 255 or you notice:
1. Increase need for inhaled quick-relief medication.
2. Increase asthma symptoms on awakening.
3. Awakening at night with asthma symtoms.
Action
Begin these medication changes:
Albuterol 2 puffs Now
Recheck Peak Flow in 30 minuets
If your symptoms/peak flows are getting worse or have not improved after repeating these steps twice, begin your Red Zone treatment.
This is less than 255 (less than 50 percent of your personal best) Danger!
Asthma symptoms are present (cough, wheeze, chest tightness).
Your peak flow number drops below_____ or you continue to get worse after increasing
Done
Local intranet